IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.:

ISPH-0755

Inventors:

Dean and Murray

Serial No.:

Not Yet Assigned

Filing Date:

Herewith

Examiner:

Not Yet Assigned

Group Art Unit:

Not Yet Assigned

Title:

Antisense Modulation of Transforming

Growth Factor- β Expression

"Express Mail" Label No. **EV331020051US** Date of Deposit_ <u>August 1, 2003</u>

I hereby certify that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Mail Stop Sequence, P. O. Box 1450, Alexandria, VA 22313-1450.

By Januassijuan

Typed Name: Jane Massey Licata, Reg. No. 32,257

Commissioner for Patents Mail Stop Sequence P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §\$1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with \$1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in \$1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

. .

- () In accordance with \$1.97(c), this Information Disclosure Statement is being filed after the period set forth in \$1.97(b) above but before the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311, therefore:
 - () Certification in Accordance with \$1.97(e) is set forth below; or
 - () The fee of \$240.00 as set forth in \$1.17(p) is attached.
- () In accordance with \$1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under \$1.113 or a Notice of Allowance under \$1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with \$1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in \$1.17(I)(1).
- () Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

(XX) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. 09/948,002 filed September 5, 2001 and 09/661,753, filed September 14, 2000, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

- () The relevance of the listed references in a foreign language is as stated in the specification at pages 00.
- (XX) All listed references are in the English language.

Respectfully submitted,

Janay Luca

Jane Massey Licata Registration No. 32,257

Date: August 1, 2003

Licata & Tyrrell P.C. 66 E. Main Street Marlton, New Jersey 08053

(856) 810-1515

Sheet **01** of **03**

| Form PTO-1449 Modified | | Docket No. ISPH-0755 | Serial No. Not yet assigned | | |
|---|--|--------------------------------|-----------------------------|--|--|
| List of Patents and Publications Cited by Applicant (Use several sheets if necessary) | | Applicant Dean and Murray | | | |
| U.S. Department of Commerce | | Filing Date Herewith | Group Not yet assigned | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | |
| AA | Arteaga et al., "Reversal of Tamoxifen Resistance of Human Breast Carcinomas In Vivo by Neutralizing Antibodies to Transforming Growth Factor- β'' , 1999 J. Nat. Cancer Inst. 91, 46-53 | | | | |
| АВ | Hoffman et al., "Potential Role of TGF-β in Diabetic nephropathy", 1998 Electrolyte Metab. 24, 190-196 | | | | |
| AC | Kim et al., "Inhibition of Wound-Induced Expression of Transforming Growth Factor-β1 mRNA by its Antisense Oligonucleotides", 1998 Pharmacol. Res. 37, 289-293 | | | | |
| AD | Kim et al., "Role of TGF-β1 on the IgE-Dependent Anaphylaxis Reaction", 1999 <i>J. Immunol.</i> 162 4960-4965 | | | | |
| AE | Liu et al., "The Transcription Factor EGR-1 Suppresses Transformation of Human Fibrosarcoma HT1080 Cells by Coordinated Induction of Transforming Growth Factor-β1, Fibronectin, and Plasminogen Activator Inhibitor-1" " 1999 J. Biol. Chem. 274, 4400-4411 | | | | |
| AF | Nakajima et al., "An Autocrine Function for Transforming Growth Factor (TGF)-β3 in the Transformation of Atrioventricular Canal Endocardium into Mesenchyme during Chick Heart Development", 1998 Japan Dev. Biol. 194, 99-113 | | | | |
| AG | Schüftan et al., " α_2 -Macroglobulin reduces paracrine-and autocrine-stimulated matrix synthesis of cultured rat hepatic stellate cells", 1999 Eur. J. Clin. Invest. 29, 519-528 | | | | |
| НА | Shen et al., "Inhibition of Transforming Growth Factor-β2 Expression with Phosphorothioate Antisense Oligonucleotides in U937 Cells", 1999 Bioorg. Med. Chem. 9, 13-18 | | | | |
| EXAMINER | | DATE CONSIDERED | | | |

Sheet **02** of **03**

| Form PTO-1449 Modified | | Docket No. ISPH-0755 | Serial No. Not yet assigned | | | |
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| U.S. Department of Commerce | | Filing Date Herewith | Group Not yet assigned | | | |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) | | | | | | |
| | AI | Tzai et al., "Antisense Oligonucleotide Specific for Transforming Growth of MBT-2 Factor-β1 Inhibit Both <i>in Vitro</i> and in Vivo Growth of MBT-2 Murine Bladder Cancer", 1998 Anticancer Res. 18, 1585-1589 | | | | |
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Docket No. Serial No. Form PTO-1449 Modified ISPH-0755 Not yet assigned List of Patents and Publications Applicant Cited by Applicant Dean and Murray (Use several sheets if necessary) Filing Date Group U.S. Department of Commerce Herewith Not yet assigned Patent and Trademark Office U. S. PATENT DOCUMENTS Subclass Examiner Document Date Name Class AA 5,683,988 11-4-97 514 44 Chung FOREIGN PATENT DOCUMENTS Translation Examiner Document No. Date Country YES NO Initial AΒ WO 94/26888 24-11-94 PCT \mathbf{x} EXAMINER DATE CONSIDERED